United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

510 S. 17th Street,
Suite 104
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

January 24, 2005

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 05-03

Subject: Implementation of the Administrative Inspection Review Program

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

The purpose of this notice is to inform interested parties of the implementation of Administrative Inspection Reviews at the Center for Veterinary Biologics (CVB) for all active licensees. At this time, permittees and applicants are not included in the Administrative Inspection Review program.

II. BACKGROUND

The Center for Veterinary Biologics, Inspection and Compliance, conducted a pilot program of the Administrative Inspection Reviews in July 2004. Three firms participated in the pilot. Their comments and suggestions were reviewed and considered for implementation in the Administrative Inspection Review program. The Administrative Inspection Review program is designed to assist the CVB and licensed firms in maintaining accurate records, facilitate more efficient on-site inspections, and enhance regulatory compliance between the licensed firms and the Animal and Plant Health Inspection Service. The CVB requests information from licensed firms for the Administrative Inspection Review program in accordance with Title 9 CFR Part 116.5(a).

III. ACTION

Approximately one-fourth of the licensed firms will be completing the administrative reviews each quarter of the fiscal year. The Administrative Inspection Review documents will be reviewed by the firms for completeness, verified for accuracy, and sent back to the CVB within 45 days. In the near term, a letter will be sent to each licensee indicating a firm's assigned quarter.

The Administrative Inspection Review consists of four sections; within each section, the firm is asked to verify production information, submit certified documents, or answer general questions about their policies and procedures. If any part of a section asks for information that is not applicable (N/A) for a licensed firm, a "N/A" response may be appropriate.

All licensees shall receive and complete the Administrative Inspection Review on an annual basis or as directed by CVB. The Administrative Inspection Review program will begin during February of 2005.

Attached is the current version of the administrative inspection review form that will be sent to each licensee.

/s/ Steven A. Karli

Steven A. Karli
Director
Center for Veterinary Biologics

ADMINISTRATIVE INSPECTION REVIEW

Section 1 – Verification of reports from the Center for Veterinary Biologics (CVB) – Licensing, Serial Release, Testing and Inspection System and other CVB databases.

Directions:
Please initial and date each previous page in the lower right corner upon review. Indicate any discrepancies by pen-and-ink. Please sign and date in the space provided on the last page of each list once verification is complete.

Part	List Title	9 CFR Reference	VS Memo/CVB Notice
A	APHIS approved Label Information	116.3(a)	
B	Current Licensed Products	102.5(c)(3)	
C	Trade Name	102.5(c)(3)	
D	Establishment Employees by Site or Establishment (APHIS Form 2007s)	114.7(a)	800.63
E	Prelicensing Activity	102.5	800.200
F	*In vitro* References	113.8(c)	800.92

Section 2 – Requested certified documents.

Directions:
Please submit the following documents to CVB; authenticate the documents by initialing and dating each page. If an item is not applicable to your firm, please specify.

Part	List Title	9 CFR Reference	VS Memo/CVB Notice
A	Organizational Chart	114.7(b)	800.91
B	Combination Products Codes with the Individual Product Codes	114.9(d)	Notice 01-04
C	Unlicensed materials/products manufactured at your firm - (e.g.) FDA Export Reform and Enhancement Act	114.1 114.2	800.94

Section 3 – General information of the firm's licensed sites:

Directions:
Please generate a short report to include all of the following applicable parts. Indicate the parts that are site specific by identifying each licensed site involved. **Authenticate** by signing and dating each page.

Part	Title	9 CFR Reference	VS Memo/CVB Notice
A	Facilities' diagnostic service location & supervisor(s) in charge	117.3(e)	

B	Responsible persons for: Primary Liaison Alternate Liaison/ Site contacts Authorized Samplers Serial Release Animal Care Facilities' manager Veterinarian on File	 114.7(a) 114.7(a) 113.3(a) 114.7(a) 117.1(b) 117.3(a)	 800.63/ Notice 02-20 800.63
C	Training plan for new employees	114.7(b)	
D	Methods for: - (e.g.) hired contractors Equipment Maintenance/ Certification Pest control Animal disposal Hazardous waste disposal	 109.2 108.10(c) 103.2/ 117.6(e) 114.15	 800.56
E	Internal Processes or Procedures for: *also indicate supervisor(s) in charge* Outline of Production review − For each product code, provide the date of last annual review − Provide a list of current Special Outlines with the date of last annual review for each Assignment of serial numbers Assignment of expiration dates Comparison of new labels to the APHIS approved Master labels	 114.8(d) 114.8(e) 114.8(e) 112.2 (a)(9) 114.13 112.5(f)	
F	Institutional Animal Care and Use Committee (IACUC) members and affiliates Animal Welfare Registration number	2.31 117.1(b)	
G	Storage of returned products (if accepted) Indicate if products are destroyed or returned to market	114.11	800.60
H	Process for documentation and review of Adverse Event Reports		
I	Biosafety committee members		800.205
J	The firm's World Wide Web address		

Section 4 – General Questions

Directions:
Please answer the following questions.

Part	Title	9 CFR Reference	VS Memo/CVB Notice
A	Does the firm maintain a comprehensive list of ingredients of animal origin?	113.53	Notice 01-14
B	If any licensed product is manufactured at multiple sites, indicate the stage of preparation and/or type of product at each licensed site for which it exclusively occurs. Examples: Bulk antigen is exclusively produced for all poultry products at Site 1. Virus X is manufactured only at Site 2. Labeling and packaging takes place exclusively at Site 2.		